Communicating with FDA: AFTER an Inspection

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Objectives

- Compliance Branch Description
- Responding to a 483
- 510k issues found during inspection

Compliance Branch Overview

Division	Director of Compliance	Compliance Officers	Recall Coordinators
1	Gina Brackett	Karen Archdeacon Ricard Cherry Amy Cramer Robert Maffei Sargum Morgan Sean Moynihan	Cynthia Aycock Andrew Lang Melinda Ruiz
2	Melissa Michurski	Wendy Blame Amy Devine Demetria Lueneburg Andrea Norwood Rafael Padilla Salvatore Randazzo David Vanhouten	Meredith Andress Marie Fink Lisa Warner
3	Jessica Mu	Ray Brullo Jamie Bumpas Charles Chacko Shaquenta Perkins Lauren Priest Jeff Wooley	Mark Chan Paul Frazier Theresa Kirkham

Compliance Branch Overview

- What do OMDRHO Compliance Officers do?
  - We respond to firm's 483 Responses
  - We prepare and execute advisory, administrative & judicial actions when necessary
  - We perform outreach activities

FDA Device Inspections

Inspection Outcomes

- NAI – No Action Indicated
- VAI – Voluntary Action Indicated
- OAI – Official Action Indicated

Regulatory Tools

- Warning Letter
- Untitled Letter
- Regulatory Meeting
- Seizure
- Injunction
- Civil Money Penalty
- Recalls, 518(e)

FY2019 QS Medical Device Inspections

Total Domestic Inspections			Total Foreign Inspection		
2847			727		
Domestic Inspection Outcomes		**%**	**Foreign Inspection Outcomes**		**%**
NAI	1625	57%	NAI	207	43%
VAI	1150	40%	VAI	245	52%
OAI	72	3%	OAI	22	5%

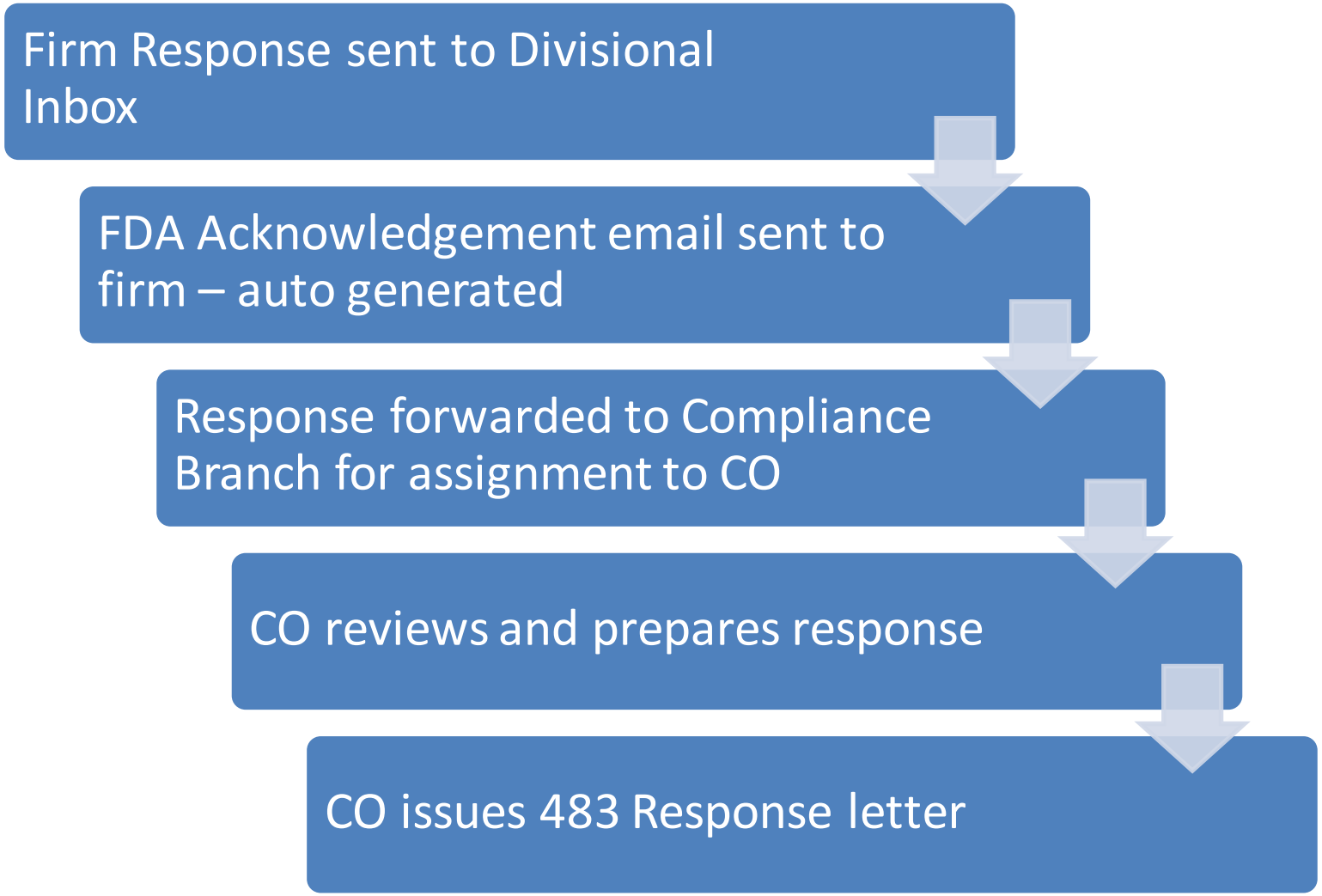
FDA 483 Responses

- Request Response within 15 Business Days
- Electronic Response preferred
- Sent to Program Compliance Branch Director
- OMDRHO will acknowledge responses

FDA 483 Responses

Division	Email
Division 1	ORA DEVICES1 Firm Response <oradevices1firmresponse@fda.hhs.gov>
Division 2	ORA DEVICES2 Firm Response <oradevices2firmresponse@fda.hhs.gov>
Division 3	ORA DEVICES3 Firm Response <oradevices3firmresponse@fda.hhs.gov>

FDA 483 Responses



Responding to OMDRHO

- Address each 483 observation / deficiency
- Provide a detailed plan of correction
- Include
  - evidence of corrections or
  - a realistic timeline for corrections if they can not be completed immediately
- Address all discussion items, including premarket issues, that were discussed during an inspection

Tips for Responding to OMDRHO

- Don’t bury Important Information!
- Use Bookmarks!
- Are the Issues Systemic?
  - Consider including a retrospective review to ensure any additional deficiencies are addressed
- Consider a Deliverable Table

Question

Has your firm historically responded to "Discussion Items" in your 483 Response?

Yes or No

510(k) Issues?

- Were changes made to your device since you received your initial 510(k) clearance?
- Have you reviewed your device for “Design Creep”?
- Have you documented your decision for not filing a new 510(k)?

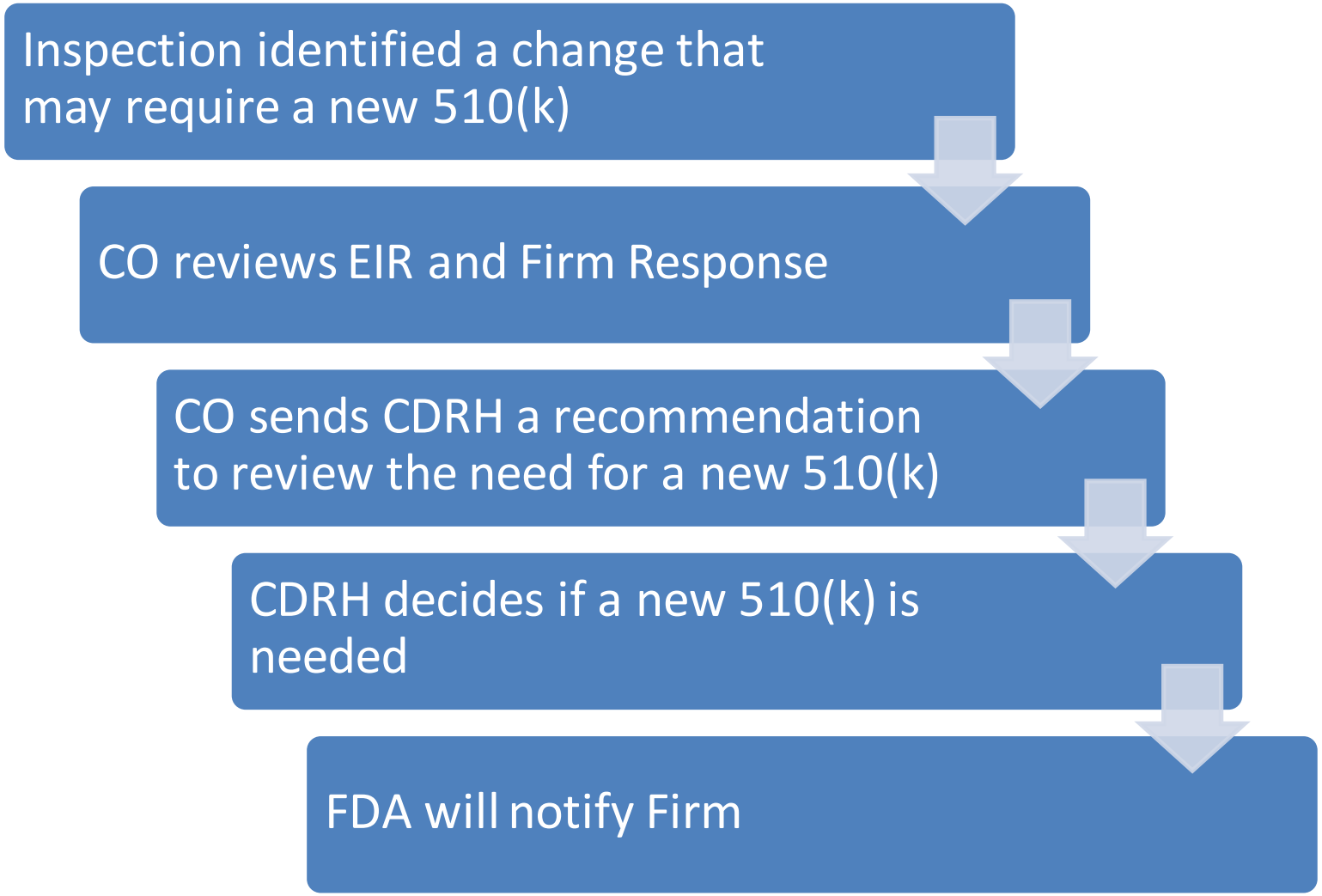
Refer to FDA’s Website – Is a new 510(k) required for a modification to the device?

Did the Inspection cover 510(k) Issues?

- Include a detailed description of your 510(k) rationale in your FDA 483 Response.

- If no 483 was issued but 510(k) items were discussed. Provide a response to the division.

Did the Inspection cover 510(k) Issues?



Resources

- **Device Advice: Comprehensive Regulatory Assistance**
- https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance

- **510(k) Information**
- Deciding When to Submit a 510(k) for a Change to an Existing Device
- Deciding When to Submit a 510(k) for a Software Change to an Existing Device

- **Device Transparency**
- https://www.fda.gov/about-fda/transparency

- **Medical Device Databases**
- https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases

Questions